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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1634	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/669,301	KUDLICKI ET AL.	
	Examiner	Art Unit	
	Arun Chakrabarti	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16,18-21,23 and 37-66* is/are pending in the application.

4a) Of the above claim(s) *24-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-16,18-21,23 and 37-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Continued Examination Under 37 CAR 1.114

1. A request for continued examination under 37 CAR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CAR 1.114, and the fee set forth in 37 CAR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CAR 1.114. Applicant's submission filed on July 30, 2002 has been entered.

Specification

2. Claims 1 and 37 have been amended. New claims 56-66 have been added.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5, 7, 9, 10, 12, 13, 15, 16, 18, 20, and 23 are rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Cazenave (Proceedings of the National Academy of Sciences (USA), (1977), Vol. 74 (11), pages 5122-5125).

Lee et al teach a method comprising:

a) obtaining at least a first soluble anti-nuclease antibody nuclease inhibitor (Figure 1 and MATERIALS AND METHODS Section, second paragraph, and Introduction, Second paragraph, first five lines);

c) obtaining a composition (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 1-5, rabbit spleen tissue in phosphate buffered saline in this case); and

d) admixing the anti-nuclease antibody and the composition to form an admixture (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 1-10).

Lee et al teach the method, wherein the nuclease inhibitor is a polyclonal anti-ribonuclease antibody and capable of binding to mRNA ribonuclease (Figure 1 and

MATERIALS AND METHODS Section, second paragraph, and Introduction, Second paragraph, first five lines).

Lee et al inherently teach the method, wherein the composition comprises at least one nuclease and RNA (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 1-10). This inherence is deduced from the fact that a freshly excised rabbit spleen naturally contains several nuclease and RNA.

Lee et al inherently teach the method, wherein the composition is a reagent used in molecular biology (MATERIALS AND METHODS Section, and RESULTS AND DISCUSSION Section). This inherence is deduced from the fact that polyribosomes (site of protein synthesis in cells) isolation is essentially under the domain of molecular biology.

Lee et al teach the method, further defined as a method of inhibiting nucleases in the composition (Page 211, lines 2-3 and MATERIALS AND METHODS Section, and RESULTS AND DISCUSSION Section).

Lee et al do not teach the method of obtaining a second soluble anti-nuclease antibody.

Cazenave teaches the method of obtaining a second soluble anti-nuclease antibody (Abstract).

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse 1 antibody.

Cazenave teaches the method, wherein the anti-ribonuclease antibody is an anti-RNAse 1 antibody (Abstract).

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse T1 antibody and anti-deoxyribonuclease antibody.

Lee et al suggest the method, wherein the anti-ribonuclease antibody is against all other nuclease present in the crude tissue (Page 212, last sentence to page 213, line 1).

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is capable of binding to micrococcal nuclease.

Cazenave teaches the method, wherein the anti-ribonuclease antibody is capable of binding to micrococcal nuclease (Page 5124, Column 1, second paragraph).

Lee et al do not teach the method, wherein the second and third nuclease inhibitor are anti-ribonuclease antibody.

Cazenave teaches the method, wherein the equivalent second and third nuclease inhibitor are anti-ribonuclease antibody. (Abstract and MATERIALS AND METHODS Section).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of inhibiting the nuclease of Lee et al., mixtures of anti-RNAse 1 antibodies of Cazenave since Lee et al state, "On the basis of this explanation, it may be suggested that the procedure for isolation of polysomes could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract (Page 212, last sentence to page 213, line 1)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Lee et al to substitute and combine, within the

method of inhibiting the nuclease of Lee et al., mixtures of anti-RNAse 1 antibodies of Cazenave in order to achieve the express advantages, as noted by Lee et al. , of a strategy which provides the procedure for isolation of polysomes that could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract.

Regarding the claimed feature of mixture of soluble anti-nuclease antibodies, applicant is hereby informed that all anti-nuclease antibodies in the claimed composition belong to same family of antibody proteins especially soluble anti-nuclease antibodies. It is obvious, in absence of unexpected results, to combine the soluble anti-nuclease antibodies for additive effect-- See MPEP 2144.06 which states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose.. The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven,* 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicant is hereby informed that combination of known function proteins is expected by one ordinary practitioner in the art to have superior results as compared with one protein.

5. Claims 11, 14, and 19 are rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Cazenave (Proceedings of the National Academy of Sciences (USA), (1977), Vol. 74 (11), pages 5122-5125) further in view of Bucala et al. (U.S. Patent 6,110,968) (August 29, 2000).

Lee et al in view of Cazenave teach method of claims 1-5, 7, 9, 10, 12, 13, 15, 16, 18, 20, and 23 as described above.

Lee et al in view of Cazenave do not teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse A antibody.

Bucala et al. teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse A antibody (Column 11, lines 14-18).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of inhibiting the nuclease of Lee et al. in view of Cazenave, an anti-RNAse A antibody of Bucala et al. since Bucala et al state, "To assess the formation of dimers, the samples were subjected to SDS-PAGE under reducing conditions, followed by transfer to cellulose and western blotting with a rabbit anti-RNAse A antibody (Column 11, lines 14-17)". Moreover Lee et al provides further motivation as Lee et al state, "On the basis of this explanation, it may be suggested that the procedure for isolation of polysomes could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract (Page 212, last sentence to page 213, line 1)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Bucala et al to substitute and combine, within the method of inhibiting the nuclease of Lee et al. in view of Cazenave, an anti-RNAse A antibody of Bucala et al. in order to achieve the express advantages, as noted by Bucala et al. , of a method which provides the assessment of the formation of dimers

between antigen and antibody and also to achieve the express advantages, as noted by Lee et al. , of a strategy which provides the procedure for isolation of polysomes that could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract.

6. Claims 6, 37-49, and 51-55 are rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Cazenave (Proceedings of the National Academy of Sciences (USA), (1977), Vol. 74 (11), pages 5122-5125) further in view of Bucala et al. (U.S. Patent 6,110,968) (August 29, 2000) further in view of Murphy et al. (BioTechnique, (1995), Vol. 18(6), pages 1069-1073).

Lee et al in view of Cazenave teach method of claims 1-5, 7, 9, 10, 12, 13, 15, 16, 18, 20, and 23 as described above.

Lee et al in view of Cazenave do not teach the method, wherein the composition is further defined as a transcription/translation reaction comprising both DNA and RNA.

Murphy et al. teach the method, wherein the composition is further defined as a transcription/translation reaction comprising both DNA and RNA.. (Abstract and MATERIALS AND METHODS Section, In vitro transcription and translation Subsection and cDNA synthesis Subsection, Page 1069).

Lee et al in view of Cazenave do not teach the method, wherein the nuclease inhibitor is human placental ribonuclease inhibitor.

Murphy et al. teach the method, wherein the nuclease inhibitor is human placental ribonuclease inhibitor (Introduction Section, Column 1, last sentence).

Lee et al in view of Cazenave do not teach the method, wherein the anti-ribonuclease antibody is capable of binding to S1 nuclease and anti-deoxyribonuclease antibody.

Lee et al suggest the method, wherein the anti-ribonuclease antibody is against all other nuclease present in the crude tissue (Page 212, last sentence to page 213, line 1).

Lee et al in view of Cazenave do not teach the method, wherein the nuclease inhibitor cocktail and a lysate are placed in the in vitro translation reaction.

Murphy et al. teach the method, wherein the nuclease inhibitor cocktail and a lysate are placed in the in vitro translation reaction. (Abstract and MATERIALS AND METHODS Section, In vitro transcription and translation Subsection, Page 1069).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of inhibiting the nuclease of Lee et al. in view of Cazenave, the nuclease inhibitor cocktail and a lysate placed in the in vitro translation reaction. of Murphy et al. since Murphy et al state, "It has a high specific activity, enhanced temperature stability, broad reaction pH range and significantly greater cost-effectiveness than commercial HPRI. Prime inhibitor is suitable for use in vitro transcription, in vitro translation, first and second-strand cDNA synthesis, preparation of RNA and mRNA, and reverse transcription polymerase chain reaction (Abstract, last two sentences)". Moreover, Lee et al state, "On the basis of this explanation, it may be suggested that the procedure for isolation of

polysomes could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract (Page 212, last sentence to page 213, line 1)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Murphy et al to substitute and combine, within the method of inhibiting the nuclease of Lee et al. in view of Cazenave, the nuclease inhibitor cocktail and a lysate placed in the in vitro translation reaction. of Murphy et al. in order to achieve the express advantages, as noted by Murphy et al. , of inhibitors which has a high specific activity, enhanced temperature stability, broad reaction pH range and significantly greater cost-effectiveness than commercial HPRI and which is suitable for use in in vitro transcription, in vitro translation, first and second-strand cDNA synthesis, preparation of RNA and mRNA, and reverse transcription polymerase chain reaction, and also in order to achieve the express advantages, as noted by Lee et al. , of a strategy which provides the procedure for isolation of polysomes that could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract.

6. Claims 56-60, and 62-66 are rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Cazenave (Proceedings of the National Academy of Sciences (USA), (1977), Vol. 74 (11), pages 5122-5125) further in view of Bucala et al. (U.S. Patent 6,110,968) further in view of Trent et al. (Journal of General Virology, (1980), Vol. 47, pages 261-282).

Lee et al. in view of Cazenave further in view of Bucala et al teach the method of claims 11, 14, and 19 as described above.

Lee et al. in view of Cazenave further in view of Bucala et al do not teach a method of obtaining an anti-RNAse T1 antibody.

Trent et al. teach a method of obtaining an anti-RNAse T1 antibody (Abstract, last paragraph and Introduction Section, last two paragraphs , and Methods Section, Isoelectric focusing of virus glycoproteins and preparation of subunit antisera subsection, and Results Section, Table 2 and Figures 3 and 4).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine a method of obtaining an anti-RNAse T1 antibody of Trent et al. within the method of inhibiting the nuclease of Lee et al. in view of Cazenave further in view of Bucala et al. since Trent et al state, "We report that long T1 oligonucleotides of WEE and HJ viruses are chemically unique (Page 262, last sentence of fourth paragraph)". Moreover, Trent et al state, "Western equine encephalomyelitis (WEE) has been recognized for nearly 50 years as a disease of humans and equine species which occurs in the central and western United States and Canada (Page 261, first sentence of Introduction Section)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Trent et al to substitute and combine a method of obtaining an anti-RNAse T1 antibody of Trent et al. within the method of inhibiting the nuclease of Lee et al. in view of Cazenave further in view of Bucala et al. in order to achieve the express advantages, as noted by

Trent et al. , of developing inhibitors against the long T1 oligonucleotides of WEE and HJ viruses that are chemically unique in order to prevent Western equine encephalomyelitis (WEE) that has been recognized for nearly 50 years as a disease of humans and equine species which occurs in the central and western United States and Canada.

Regarding the claimed feature of mixture of soluble anti-nuclease antibodies, applicant is hereby informed that all anti-nuclease antibodies in the claimed composition belong to same family of antibody proteins especially soluble anti-nuclease antibodies. It is obvious, in absence of unexpected results, to combine the soluble anti-nuclease antibodies for additive effect-- See MPEP 2144.06 which states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose.. The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven,* 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicant is also hereby informed that combination of known function proteins is expected by one ordinary practitioner in the art to have superior results as compared with one protein.

7. Claim 61 is rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Cazenave (Proceedings of the National Academy of Sciences (USA), (1977), Vol. 74 (11), pages 5122-5125) further in view of Bucala et al. (U.S. Patent

6,110,968) further in view of Trent et al. (Journal of General Virology, (1980), Vol. 47, pages 261-282) further in view of Murphy et al. (BioTechnique, (1995), Vol. 18(6), pages 1069-1073).

Lee et al. in view of Cazenave further in view of Bucala et al further in view of Trent et al teach the method of claims 56-60, and 62-66 as described above.

Lee et al. in view of Cazenave further in view of Bucala et al further in view of Trent et al do not teach the method wherein the nuclease inhibitor cocktail and a lysate are placed in the in vitro translation reaction.

Murphy et al. teach the method, wherein the nuclease inhibitor cocktail and a lysate are placed in the in vitro translation reaction. (Abstract and MATERIALS AND METHODS Section, In vitro transcription and translation Subsection, Page 1069).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of inhibiting the nuclease of Lee et al. in view of Cazenave further in view of Bucala et al further in view of Trent et al, the nuclease inhibitor cocktail and a lysate placed in the in vitro translation reaction. of Murphy et al. since Murphy et al state, "It has a high specific activity, enhanced temperature stability, broad reaction pH range and significantly greater cost-effectiveness than commercial HPRI. Prime inhibitor is suitable for use in in vitro transcription, in vitro translation, first and second-strand cDNA synthesis, preparation of RNA and mRNA, and reverse transcription polymerase chain reaction (Abstract, last two sentences)". Moreover, Lee et al state, "On the basis of this explanation, it may be suggested that the procedure for isolation of polysomes could be further

improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract (Page 212, last sentence to page 213, line 1)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Murphy et al to substitute and combine, within the method of inhibiting the nuclease of Lee et al. in view of Cazenave further in view of Bucala et al further in view of Trent et al, the nuclease inhibitor cocktail and a lysate placed in the in vitro translation reaction. of Murphy et al. in order to achieve the express advantages, as noted by Murphy et al. , of inhibitors which has a high specific activity, enhanced temperature stability, broad reaction pH range and significantly greater cost-effectiveness than commercial HPRI and which is suitable for use in in vitro transcription, in vitro translation, first and second-strand cDNA synthesis, preparation of RNA and mRNA, and reverse transcription polymerase chain reaction, and also in order to achieve the express advantages, as noted by Lee et al. , of a strategy which provides the procedure for isolation of polysomes that could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract.

Response to Amendment

8. In response to amendment, all previous 103(a) rejections are maintained and new 103 (a) rejections have been included.

Response to Arguments

9. Applicant's arguments filed on August 5, 2002 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Lee reference does not teach the soluble antibodies of the claimed invention. Applicant argues that the word "soluble" was not found in Lee reference and only the word "insoluble" is found. Applicant argues that because Lee has a preferred embodiment of insoluble antibodies, Lee is limited to the preferred embodiment. This argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi,169 USPQ 423 (CCPA 1971)." MPEP 2123 also states " A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories , 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Lee has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. Although Lee reference uses insoluble antibodies (final product) to isolate the polysomes the property of soluble antibody (initial product) is inherently

present in this chemically and structurally identical molecule. For example, Lee suggests that soluble antibodies directed against a crude preparation of nucleases could be insolubilized by cross linking with EMA (Page 213, lines 3-4). It is evident that at certain stage of antinuclease antibody preparation of Lee, antibodies remain soluble. Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater,* 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this case, any antinuclease (RNAse) antibody at any stage of preparation can be used for the purpose of inhibiting the breakdown of RNA.

Applicant then argues the 103 rejection is improper because the method of Lee lacks a reasonable expectation of success in any method other than the isolation of polysome.

With regard to the lack of reasonable expectation of success argument, The MPEP 2143.02 states, "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart , 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference

which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also Amgen, Inc. v. Chugai Pharmaceutical Co ., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied , 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success. 18 USPQ2d at 1022, 1023.); In re O'Farrell , 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.)."

There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There are evidence and suggestion in the Lee reference of the enabling methodology, the suggestion to modify the prior art, and evidence that a number of different RNAse antibodies were actually experimentally studied to inhibit the RNAse activities of spleen cells and found to be functional (Figure 1). This evidence of functionality trumps the attorney arguments, which argues that Lee reference is an invitation to research, since Lee steps beyond research and shows the functional product. Moreover, an ordinary artisan would reasonably expect the inhibition of an enzyme by its antibody under any suitable environment.

In view of the response to argument, all previous 103(a) rejections are maintained.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

August 12, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600